

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	8
-------	---	----	---

Complete if Known

Application Number	10/538,991-Conf. #4267
Filing Date	April 9, 2007
First Named Inventor	Thomas SMITH
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	0112981.00126US1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code 2 (if known)			
AA*	US-2,515,898	07-18-1950	Rhodeshamel		
AB*	US-2,627,491	02-03-1953	Szabo et al.		
AC*	US-3,867,519	02-18-1975	Michaels		
AD*	US-3,993,073	11-23-1976	Zaffaroni		
AE*	US-4,105,776	06-08-1978	Onetti et al.		
AF*	US-4,231,938	11-04-1980	Monaghan et al.		
AG*	US-4,316,906	02-23-1982	Onetti et al.		
AH*	US-4,337,201	06-29-1982	Petrillo, Jr.		
AI*	US-4,344,949	08-17-1982	Hoefle et al.		
AJ*	US-4,346,227	08-24-1982	Terahara et al.		
AK*	US-4,374,829	02-22-1983	Harris et al.		
AL*	US-4,410,520	10-18-1983	Watthey		
AM*	US-4,439,196	03-27-1984	Higuchi		
AN*	US-4,444,784	04-24-1984	Hoffman et al.		
AO*	US-4,508,729	04-02-1985	Vincent et al.		
AP*	US-4,512,924	04-23-1985	Attwood et al.		
AQ*	US-4,587,258	05-06-1986	Gold et al.		
AR*	US-4,652,441	03-24-1987	Okada et al.		
AS*	US-4,675,196	06-23-1987	Villa et al.		

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and consider. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with a single asterisk (*) next to the Cite No. are not supplied under 37 CFR 1.58(e)(2)(iii) because that application was filed after June 30, 2003 or is available in the IFW. * Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEI 901.4. * Enter office that issued the patent. * PRIORITY: Indicate priority date and country. * JPN: For Japanese patent numbers, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind Code: The kind code symbol as indicated on the document under the WIPO Standard ST.16 is possible. * Applicant is to place a check mark here if English language translation is attached.

Substitute for form 1449A/PTO

(Use as many sheets as necessary)

Sheet	2	of	8
-------	---	----	---

Application Number	10/538,991-Conf. #4267
Filing Date	April 9, 2007
First Named Inventor	Thomas SMITH
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	0112981.00126US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Column, Lines, Where Relevant Passage or Relevant Figures Appear
		Number-Kind Code (# known)	MM-DD-YYYY		
	AT*	US-4,739,073	04-19-1988	Kathawala	
	AU*	US-4,757,128	07-12-1988	Domb et al.	
	AV*	US-4,789,724	12-06-1988	Domb et al.	
	AW*	US-4,857,311	08-15-1989	Domb et al.	
	AX*	US-4,888,176	12-19-1989	Langer et al.	
	AY*	US-4,897,402	01-30-1990	Duggan et al.	
	AZ*	US-4,904,646	02-27-1990	Karanewsky et al.	
	AA1*	US-4,906,624	03-06-1990	Chucholowski et al.	
	AB1*	US-4,906,657	03-06-1990	Roth	
	AC1*	US-4,920,109	04-24-1990	Onishi et al.	
	AD1*	US-4,923,861	05-08-1990	Picard et al.	
	AE1*	US-4,929,620	05-29-1990	Chucholowski et al.	
	AF1*	US-4,939,143	07-03-1990	Regan et al.	
	AG1*	US-4,940,727	07-10-1990	Inamine et al.	
	AH1*	US-4,940,800	07-10-1990	Bertolini et al.	
	AI1*	US-4,946,860	08-07-1990	Morris et al.	
	AJ1*	US-4,946,864	08-07-1990	Prugh et al.	
	AK1*	US-4,950,675	08-21-1990	Chucholowski	
	AL1*	US-4,957,940	09-18-1990	Roth	

[illegible]

Examiner
Signature

Date	
Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with a single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after October 30, 2003 or is available in the IFW. * Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP § 601.04. * Enter office that issued the application. If the Office is a Foreign Office, the indication of the year of the origin of the invention must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. If possible, * Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/APTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/538,991-Conf. #4267	
			Filing Date	April 9, 2007	
			First Named Inventor	Thomas SMITH	
			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	8	Attorney Docket Number	0112981.00126US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number/Kind Code ² (if known)			
	AM1*	US-4,963,538	10-16-1990	Duggan et al.	
	AN1*	US-4,968,693	11-06-1990	Joshua et al.	
	AO1*	US-4,970,231	11-13-1990	Lee et al.	
	AP1*	US-4,992,429	02-12-1991	Ullrich et al.	
	AQ1*	US-4,994,281	02-19-1991	Muranishi et al.	
	AR1*	US-4,994,494	02-19-1991	Regan et al.	
	AS1*	US-4,996,234	02-26-1991	Regan et al.	
	AT1*	US-4,997,837	03-05-1991	Chucholowski et al.	
	AU1*	US-5,001,128	03-19-1991	Neuenschwander et al.	
	AV1*	US-5,001,144	03-19-1991	Regan et al.	
	AW1*	US-5,017,716	05-21-1991	Karanewsky et al.	
	AX1*	US-5,021,453	06-04-1991	Joshua et al.	
	AY1*	US-5,025,000	06-18-1991	Karanewsky	
	AZ1*	US-5,081,136	01-14-1992	Bertolini et al.	
	AA2*	US-5,091,378	02-25-1992	Karanewsky et al.	
	AB2*	US-5,091,386	02-25-1992	Kesseler et al.	
	AC2*	US-5,098,931	03-24-1992	Duggan et al.	
	AD2*	US-5,102,911	04-07-1992	Lee et al.	
	AE2*	US-5,112,857	05-12-1992	Vickers	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IPW. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			Complete if known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/538,991-Conf. #4267	
			Filing Date	April 9, 2007	
			First Named Inventor	Thomas SMITH	
			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	4	of	8	Attorney Docket Number	0112981.00126US1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AF2*	US-5,116,870	05-26-1992	Smith et al.	
	AG2*	US-5,130,306	07-14-1992	Duggan et al.	
	AH2*	US-5,132,312	07-21-1992	Regan et al.	
	AI2*	US-5,135,935	08-04-1992	Alberts et al.	
	AJ2*	US-5,166,171	11-24-1992	Jendrala et al.	
	AK2*	US-5,182,298	01-26-1993	Helms et al.	
	AL2*	US-5,196,440	03-23-1993	Bertolini et al.	
	AM2*	US-5,202,327	04-13-1993	Robl	
	AN2*	US-5,250,435	10-05-1993	Cover et al.	
	AO2*	US-5,256,689	10-26-1993	Chiang	
	AP2*	US-5,260,332	11-09-1993	Dufresne	
	AQ2*	US-5,262,435	11-16-1993	Joshua et al.	
	AR2*	US-5,271,946	12-21-1993	Hettche et al.	
	AS2*	US-5,273,995	12-28-1993	Roth	
	AT2*	US-5,276,021	01-04-1994	Karanevsky et al.	
	AU2*	US-5,283,256	02-01-1994	Dufresne et al.	
	AV2*	US-5,286,895	02-15-1994	Harris et al.	
	AW2*	US-5,302,604	04-12-1994	Byrne et al.	
	AX2*	US-5,317,031	05-31-1994	MacConnell et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†
		Country Code ³ -Number ⁴ -Kind Code ² (if known)				

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitution for form 1449A/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>				<p style="text-align: right;">Complete if Known</p> <table border="1"> <tr> <td>Application Number</td> <td>10/538,991-Conf. #4267</td> </tr> <tr> <td>Filing Date</td> <td>April 9, 2007</td> </tr> <tr> <td>First Named Inventor</td> <td>Thomas SMITH</td> </tr> <tr> <td>Art Unit</td> <td>1614</td> </tr> <tr> <td>Examiner Name</td> <td>Not Yet Assigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>0112981.00126US1</td> </tr> </table>		Application Number	10/538,991-Conf. #4267	Filing Date	April 9, 2007	First Named Inventor	Thomas SMITH	Art Unit	1614	Examiner Name	Not Yet Assigned	Attorney Docket Number	0112981.00126US1
Application Number	10/538,991-Conf. #4267																
Filing Date	April 9, 2007																
First Named Inventor	Thomas SMITH																
Art Unit	1614																
Examiner Name	Not Yet Assigned																
Attorney Docket Number	0112981.00126US1																
Sheet	5	of	8														

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference concise, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not concurred. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that patent was filed after June 30, 2003 or is included in the IFW. *Applicants unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *Enter Office that issued the cited document. If the cited document is a foreign publication, the indicia of the year of the WIPO of the design of the Employer must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/538,991-Conf. #4267
				Filing Date	April 9, 2007
				First Named Inventor	Thomas SMITH
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	6	of	8	Attorney Docket Number	0112981.00126US1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	ADAMS et al., Depot fluphenazine for schizophrenia, <i>Cochrane Database Syst. Rev.</i> 2000	
	CB	ARNSTEN et al., Antiretroviral therapy adherence and viral suppression in HIV-infected drug users: comparison of self-report and electronic monitoring, <i>Clin. Infect. Dis.</i> , 2001, pp.1417-23, 33(8)	
	CC	BARTLETT et al., Management of Anthrax, <i>Clinical Infectious Diseases</i> , 2002, pp.851-85, 35	
	CD	BLAUW et al., Stroke statins and cholesterol, A meta-analysis of randomized, placebo-controlled, double-blind trials with HMG-CoA reductase inhibitors, <i>Stroke</i> 1997, pp.946-50, 28(5)	
	CE	BURCH et al., Current indications for ACE inhibitors and HOPE for the future, <i>Am. J. Mang. Care</i> , 2002, pp.478-90, quiz 491-3, 8(5)	
	CF	BYRON et al., Effects of heat treatment on the permeability of polyvinyl alcohol films to a hydrophilic solute, <i>J. Pharm. Sci.</i> , 1987, pp.65-67, 76(1)	
	CG	CADORNIGA et al., In vitro evaluation of the dissolution rate of crystalline suspensions destined to intramuscular administration, <i>Eur. J. Drug Metab. Pharmacokin.</i> , 1991, pp.379-84, Spec. No. 3	
	CH	CROWDER et al., A Guide to Pharmaceutical Particulate Science, 2003, CRC Press, pgs. 9-26	
	CI	CUSHENBERRY et al., Potential use of HMG-CoA reductase inhibitors for osteoporosis, <i>Ann. Pharmacother.</i> , 2002, pp.671-8, 36(4)	
	CJ	DECHEND et al., Modulating angiotensin II-induced inflammation by HMH Co-A reductase inhibition, <i>Am. J. Hypertens.</i> , 2001, pp.55S-61S, 14(6 Pt2)	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 5px 0;">(Use as many sheets as necessary)</p>				Complete if Known	
Application Number				10/538,991-Conf. #4267	
Filing Date				April 9, 2007	
First Named Inventor				Thomas SMITH	
Art Unit				N/A	
Examiner Name				Not Yet Assigned	
Attorney Docket Number				0112981.00126US1	

Sheet	7	of	8
-------	---	----	---

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CK	ENDRES et al., Stroke protection by 3-hydroxy-3-methylglutaryl (HMG)-CoA reductase inhibitors mediated by endothelial nitric oxide synthase, Proc. Nat. Acad. Sci. USA, 1998, pp.8880-5, 95	
	CL	FASSBENDER et al., Effects of statins on human cerebral cholesterol metabolism and secretion of alzheimer amyloid peptide [in process citation], Neurology, 2002, pp.1257-8, 59(8)	
	CM	FLECKENSTEIN, History of calcium antagonists, Cir. Res./Suppl. 1, 1983, pp.1-3 - I-16, 52(2)	
	CN	FRIEDLANDER et al., Postexposure prophylaxis against experimental inhalation anthrax, J. Infect. Dis., May 1993, pp.1239-43, 167(5)	
	CO	GHARABAWI et al., Enhanced psychiatric and neurological outcomes in chronically psychotic patients treated for a year with long-acting, injectable risperidone, Proc. Ann. Meeting Am. College of Neuropsychopharmacology, 2002, San Juan PR	
	CP	HOUGHTON, Angiotensin II receptor antagonists in chronic heart failure: where to they fit?, Drugs, 2002, pp.1433-40, 62(10)	
	CQ	JEFFERDS et al., Adherence to antimicrobial inhalational anthrax prophylaxis among postal workers, Emerging Infectious Diseases, 2002, pp.1138-1144, 8(10)	
	CR	KAPLAN et al., Pharmacokinetics of benzathine penicillin G: serum levels during the 28 days after intramuscular injection of 1,200,000 units., J. Pediatr., 1989, pp.146-50, 115(1)	
	CS	MCCALL et al., Calcium entry blocking drugs: Mechanisms of action, experimental studies and clinical uses, Curr. Probl. Cardiol., 1985, pp.1-80	
	CT	MIMRAN et al., Angiotensin II receptor antagonists and hypertension, Clin. Exp. Hypertens., 1999, pp.847-58, 21(5-6)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/538,991-Conf. #4267	
			Filing Date	April 9, 2007	
			First Named Inventor	Thomas SMITH	
			Art Unit	N/A	
			Examiner Name	Not Yet Assigned	
Sheet	8	of	8	Attorney Docket Number	0112981.00126US1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	CU	MOLLMANN et al., Clinical and pharmacologic aspects of various betamethasone crystalline suspensions, <i>fortsch. Med.</i> , 1977, pp.972-8, 95(14)		
	CV	O'KEEFE et al., Should an angiotensin-converting enzyme inhibitor be standard therapy for patients with atherosclerotic disease?, <i>J. Am. Coll. Cardiol.</i> , pp.1-8, 37(1)		
	CW	PERICO et al., Angiotensin II receptor antagonists and treatment of hypertension and renal disease, <i>Curr. Opin. Nephrol. Hypertens.</i> , 1998, pp.571-8, 7(5)		
	CX	QURAIISHI et al., Depot haloperidol decanoate for schizophrenia, <i>Cochrane Database Syst. Rev.</i> 2000		
	CY	Remington: The Science and Practice of Pharmacy, p. 1371		
	CZ	Remington: The Science and Practice of Pharmacy, p.963, 19th Edition		
	CA1	Table 16-1, Remington: The Science and Practice of Pharmacy, 2000, p.209, 20th Ed.		
	CB1	WONG et al., Nonpeptide angiotensin II receptor antagonists I. Pharmacological characterization of 2-n-butyl-4-chloro-1-(2-chlorobenzyl)imidazole-5-acetic acid, sodium salt (S-8307), <i>J. Pharmacol. Exp. Ther.</i> , 1988, pp.1-7, 247(1)		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.